Complete Summary

GUIDELINE TITLE

Standards for the management of ductal carcinoma in situ of the breast (DCIS).

BIBLIOGRAPHIC SOURCE(S)

Standards for the management of ductal carcinoma in situ of the breast (DCIS). CA Cancer J Clin 2002 Sep-Oct;52(5):256-76. [104 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Ductal carcinoma in situ (DCIS) of the breast

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management

CLINICAL SPECIALTY

Oncology
Pathology
Radiation Oncology
Radiology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To guide physicians in the diagnosis and management of ductal carcinoma in situ (DCIS) of the breast
- To update the 1997 recommendations on the diagnosis and management of ductal carcinoma in situ of the breast [CA Cancer J Clin 1998 Mar/Apr;48(2):108-28]

TARGET POPULATION

Patients with ductal carcinoma in situ of the breast

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis and evaluation

1. History and physical examination
2. Mammographic evaluation
3. Surgical biopsy
4. Pathologic evaluation

Treatment Options

1. Mastectomy
2. Breast-conserving surgery (lumpectomy) and radiation therapy
3. Breast-conserving surgery alone
4. Role of Tamoxifen

MAJOR OUTCOMES CONSIDERED

- Breast cancer mortality
- Rate of invasive breast cancer recurrence
- Psychological outcomes following breast cancer surgery including global measures of emotional distress and quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE is the principle database used for search of peer-reviewed journals for articles related to the proposed standard.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each standard, representing a policy statement by the American College of Radiology, has undergone a thorough consensus process in which it has been subjected to extensive review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Standards were approved by the American College of Radiology, the American College of Surgeons, the Society of Surgical Oncology, and the College of American Pathologists.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Treatment selection for the individual patient with ductal carcinoma in situ (DCIS) requires a clinical, mammographic, and pathologic evaluation. The term DCIS encompasses a heterogeneous group of lesions, and prior to the determination of a patient's suitability for breast conservation with or without irradiation or the necessity of mastectomy, a thorough evaluation to characterize the extent and character of the patient's disease is necessary.

Patient Evaluation

An adequate history and physical examination will include a complete assessment of the patient's overall health status. Much of the information needed to determine a patient's suitability for breast conservation therapy can be obtained from a directed history and physical examination.

The elements of the breast cancer's specific history and physical examination are listed in Tables 1 and 2 in the original guideline document and represent information that may affect the selection of local therapy.

Mammographic Evaluation

Recent mammographic evaluation (usually within 3 months) prior to biopsy or definitive surgery is needed to establish the appropriateness of breast conservation treatment by defining the extent of the patient's disease. In addition to mediolateral oblique and craniocaudal views, magnification views should be obtained routinely to identify areas of calcified tumor elsewhere in the breast that otherwise might not be apparent. Magnifications or spot-compression magnification views increase imaging resolution for better depiction of shapes of calcifications and their number and extent.

The preoperative diagnosis of DCIS can be suggested by mammography, but a definitive diagnosis depends on pathologic evaluation of the specimen. Imaging techniques are not reliable to determine whether or not the basement membrane has been violated, and peritumoral inflammation and/or fibrosis can cause a mass to be present along with microcalcifications in the absence of invasion. The subtypes of DCIS, nuclear grade, and extent of necrosis can be suggested on the basis of characteristic patterns of calcifications, but these patterns are not diagnostic, and the definitive diagnosis depends on the analysis of tissue by the pathologist.

The mammogram may underestimate the extent of DCIS. Underestimation is increasingly likely with increasing lesion size. However, an effort should be made to determine the extent of tumoral calcifications preoperatively in all cases, and the maximal span of the calcifications should be reported. If a mass is present it should be measured. The size of low- and intermediate-grade DCIS is underestimated by 2-cm in as many as 50% of cases when only two-view mammography is performed. The routine use of magnification views, as well as other special views as required, will significantly reduce the likelihood of this

problem. The entire breast should be carefully examined to determine if areas of tumor are present elsewhere in the breast, thereby influencing a decision about breast-conserving treatment.

The contralateral breast should also be evaluated, and bilateral mammography is required. Bilateral DCIS was found in 19% (7 of 36) women with DCIS who underwent contralateral subcutaneous mastectomy in one study.

The role of other images modalities, especially MRI, has yet to be established for DCIS. Contrast-enhanced MRI is very sensitive for invasive cancers, but DCIS has nonspecific appearances and kinetic enhancement curves that can mimic fibrocystic changes and other benign findings.

Surgical Considerations

When breast conservation treatment is appropriate, the goals of any surgical procedure on the breast are total removal of the suspicious or known malignant tissue and minimal cosmetic deformity. These goals apply to both diagnostic biopsy and definitive local excision. Failure to consider them at all stages may jeopardize conservation of the breast.

DCIS presenting as a palpable mass can occur but is unusual. The surgical techniques described for the evaluation and excision of palpable invasive disease apply to palpable DCIS. The most common presentation of DCIS is microcalcifications. Thus, image-directed procedures are necessary for diagnosis and treatment.

Details about stereotactic core-needle and guided wire open biopsy procedures are provided in the original guideline document.

Re-excision of Biopsy Site

Re-excision of the previous biopsy site must be performed carefully to assure negative margins of resection, avoid excess breast tissue removal, and achieve good cosmesis. If microcalcifications are the indication for re-excision, needle localization should be considered. Proper orientation of the original biopsy specimen will allow identification of the individual margin surfaces involved with tumor. Re-excision can be limited to these areas. When the specimen has not been oriented, removal of a rim of tissue around the previous biopsy is necessary.

Management of the Axilla

Axillary nodal metastases occur in fewer than 5% of patients with DCIS and are due to the presence of unrecognized invasive carcinoma. As many as 20% of patients diagnosed as having DCIS with an image-guided breast biopsy will have invasive carcinoma identified when the entire lesion is removed. Invasion is more likely in association with extensive high-grade DCIS or when a mass is present on the mammogram. In patients treated with breast-conserving therapy, the need for axillary sampling can be assessed after the lesion has been completely removed and evaluated for the presence of invasive carcinoma. If invasive tumor is found, these patients are candidates for sentinel node biopsy or axillary

dissection. The presence of a surgical biopsy cavity has not been found to be a contraindication to lymphatic mapping. In patients with large DCIS lesions requiring mastectomy, sentinel node biopsy should be considered when invasion has not been documented since the procedure cannot be performed after a mastectomy. The mapping agent can be injected around the DCIS lesion or in the periareolar region since the precise location of any invasive carcinoma is not known.

For surgeons inexperienced in lymphatic mapping, consideration should be given to performance of a level I axillary dissection at the time of mastectomy (particularly if immediate reconstruction is done) to avoid a second operation. Some authors have suggested that lymphatic mapping and sentinel node biopsy with immunohistochemistry should be carried out in all patients with DCIS. Pendas et al reported that 5 of 87 patients (6%) with pure DCIS had metastatic disease to the sentinel node, which was detected by immunohistochemistry only in 3 cases. No additional nodal metastases were found on completion dissection. All involved nodes occurred in patients with large or high-grade DCIS. Since the prognostic significance of immunohistochemically positive cells in the sentinel node remains a matter of debate, and since long-term survival rates of 97%-99% for DCIS patients treated by surgery alone are not compatible with a significant incidence of axillary nodal metastases, the guideline developers favor a selective approach to the axillary nodes as described.

Pathologic Evaluation

Tissue Handling

The excised tissue should be submitted for pathology examination with appropriate clinical history and anatomic site specifications, including laterality (right or left breast) and quadrant. For wide excisions or segmental breast resections, the surgeon should orient the specimen (e.g., superior, medial, lateral) for the pathologist with sutures or other markers. The specimen radiograph should be available for the pathologist to review while examining the specimen.

Gross examination should document the type of surgical specimen when this information is provided to the pathologists (e.g., excisional biopsy, quadrantectomy), the size of the specimen, and the proximity of the tumor (if visible) or biopsy site to the margins of excision. The presence or absence of tumor at the margins of excision is determined by marking them with India ink or using another suitable technique. In general, the entire mammographic lesion, and as much of the remaining specimen as practical, should be submitted for histologic examination. Additionally, the margins of the specimen must be thoroughly evaluated, particularly those closest to the lesion.

Frozen section examination of image-guided needle biopsies of nonpalpable lesions or mammographically directed biopsies done for microcalcifications is strongly discouraged. Distinguishing between atypical ductal hyperplasia and DCIS may be impossible in frozen-section preparations, and small foci of microinvasion may be lost or rendered uninterpretable by freezing artifact. In general, frozen sections should be prepared only when there is sufficient tissue that the final

diagnosis will not be compromised (i.e., grossly visible tumors larger than 1.0 cm) and when the information is necessary for immediate therapeutic decisions.

Pathologic Features Influencing Treatment Choice

A consensus conference on the classification of DCIS was convened in 1997. Although a single classification system for DCIS was not endorsed at this meeting, it was recommended that the pathologist should clearly report the nuclear grade of the lesion and the presence or absence of necrosis and cell polarization. Because of the recognition of the importance of nuclear grade, this was defined in detail in the consensus document. If a specific grading system for DCIS is used, this should be stated in the pathology report. The report also should include the architectural patterns present, since this may have clinical relevance (e.g., the micropapillary pattern may be more prone to involvement of multiple quadrants, independent of nuclear grade).

A few recent studies have addressed the issue of consistency among pathologists in categorizing DCIS using the newer classification systems. In general, greatest consistency is achieved using classification systems based primarily on nuclear grade.

Knowledge of the extent (size) of DCIS is important in deciding treatment, but in contrast to most invasive cancers, measuring the size of DCIS is difficult because it is usually nonpalpable and cannot be identified grossly. While a precise measurement of size may not be possible, the pathologist may be able to estimate the extent of DCIS, and this information should be included in the pathology report. Several methods for estimating the extent (size) of DCIS are noted in the original guideline document.

The assessment of surgical margins is arguably the most important aspect in the pathologic evaluation of breast tumor excisions in patients with DCIS being considered for breast conservation. Although the definitions of "positive" and "negative" margins vary among institutions, microscopic extension of DCIS to surgical margins usually results in further surgery. The pathologist should clearly specify in the pathology report whether DCIS is transected at the surgical margin, and if not, how close the lesion is to the nearest margin.

In contrast to DCIS, lobular carcinoma in situ (LCIS, lobular neoplasia) is an incidental histologic finding that is considered a marker of increased risk for subsequent breast cancer rather than a malignant lesion requiring surgical excision. This increase in risk applies to both breasts and is probably lifelong. The relation between LCIS and surgical margins is not important. The management of patients with recently recognized histological variants of LCIS (such as pleomorphic LCIS) has not been defined due to lack of information about the natural history of such lesions.

HER2/neu gene amplification/protein overexpression is not necessary for the routine evaluation of noninvasive breast carcinomas. Recent data from the National Surgical Adjuvant Breast and Bowel Project (NSABP) B24 trial indicate that the addition of tamoxifen to local excision and radiation decreases the risk of local recurrence. However, the role of estrogen and progesterone receptors in selecting DCIS patients for tamoxifen therapy has not been evaluated.

The Pathology Report

Certain pathologic features should be included in the surgical pathology consultation report because they help determine the most appropriate therapy. These features include:

1. How the specimen was received (e.g., number of pieces, fixative, orientation).
2. The laterality and quadrant of the excised tissue and the type of procedure, as specified by the surgeon.
3. Size of the specimen in three dimensions.
4. Whether the entire specimen was submitted for histologic examination.
5. The histologic features of DCIS (e.g., nuclear grade, necrosis, architectural pattern).
6. An estimate of the extent or size of DCIS (if possible).
7. The location of microcalcifications (e.g., in DCIS, in benign breast tissue, or both).
8. The presence or absence of DCIS at the margins of excision. If possible, the distance of the lesion or biopsy site from the margin should be stated.

The use of a synoptic report summarizing key features such as tumor size, grade, and margin status in a list is highly recommended.

Selection of Treatment

It is the collective responsibility of the surgeon, pathologist, radiation oncologist, and radiologist to integrate all available data in order to clearly articulate treatment options and recommendations to the patient. The treatment team must decide, on the basis of imaging studies, the physical exam, and the pathology report, whether the patient is a candidate for a breast-conserving approach. If so, further discussion regarding the issue of local recurrence must be conducted. Local recurrence with total mastectomy is rare. Local recurrence is observed at a higher rate in patients treated with breast conservation, but the impact of these local recurrences on overall survival is small. Finally, patients need to understand the excellent prognosis for this disease with either surgical approach.

Treatment Options

Indications for Mastectomy

Although many women with DCIS are candidates for breast-conserving treatment with or without irradiation, there are some patients for whom mastectomy is clearly indicated. These include:

a. Women with two or more primary tumors in the breast or with diffuse, malignant-appearing microcalcifications.
b. Persistent positive margins after reasonable surgical attempts.

In addition, there are some women for whom the risk/benefit ratio of breast conservation must be carefully assessed, and consideration must be given to mastectomy as a treatment alternative.

Neither tumor size nor histologic type of DCIS is an absolute indication for mastectomy. However, a relative indication for mastectomy is the presence of extensive DCIS that can be removed with only a small negative margin. This is particularly true in a patient with a small breast in which an adequate resection would result in a significant cosmetic alteration that is unacceptable to the patient.

Indications for Breast-Conserving Surgery and Radiation Therapy

Indications for breast-conserving surgery and radiation therapy

a. DCIS detected mammographically or by physical exam that is localized (without evidence of gross multicentricity or diffuse malignant calcifications).
b. The extent of DCIS should be $\leq$ 4 cm as there is little data to support breast conservation's effectiveness in larger lesions. The difficulty in measuring the size of DCIS makes definitive recommendations difficult.

For mammographically detected DCIS presenting as microcalcifications, all malignant calcifications must be removed prior to the initiation of radiation. Negative margins of resection are important to minimize the ipsilateral breast tumor recurrence rate in patients with DCIS.

Certain factors preclude the use of radiation in the treatment of patients with DCIS and are unrelated to the extent of the disease. These include a history of collagen vascular disease (especially scleroderma and lupus erythematosus), prior therapeutic radiation to the breast and/or chest, and pregnancy. The first two factors are related to the potential for significant morbidity, and the last is related to radiation exposure to the fetus.

Indications for Breast-Conserving Surgery Alone

Individual centers have suggested a low local recurrence rate for low-grade tumors of small volume excised with clear margins, but the maximum size of DCIS for which radiation therapy could be safely omitted is unknown. Two randomized trials have demonstrated risk reduction with radiation for all subgroups of DCIS patients studied, but for some groups the absolute benefit of radiation is very small. The patient´s attitude toward risks and benefit should play a major factor in the decision to omit radiation in these cases.

Patient Choice Issues

Perhaps the most difficult aspect of patient evaluation is the assessment of the patient's needs and expectations regarding breast preservation. The patient and her physician must discuss the benefits and risks of mastectomy compared with breast conservation treatment in her individual case, with thoughtful consideration of each. Each woman must evaluate how her choice of treatment is likely to affect her sense of disease control, self-esteem, sexuality, physical functioning, and overall quality of life. A number of factors should be considered:

1. Long-term survival.
2. The possibility and consequences of local recurrence.

3. Psychological adjustment (including the fear of cancer recurrence and attitudes toward radiation), cosmetic outcome, sexual adaptation, and functional competence.

For most patients, the choice of mastectomy with or without reconstruction or breast-conservation treatment does not impact on the likelihood of survival, but it may have a differential effect on the quality of life. Psychological research comparing patient adaptation after mastectomy and breast conservation treatment shows no significant differences in global measures of emotional distress. Research also does not reveal significant changes in sexual behavior and erotic feelings in the treated breast or nipple and areolar complex. However, women whose breasts are preserved have more positive attitudes about their body image and experience fewer changes in their frequency of breast stimulation and feelings of sexual desirability.

Radiation Therapy Considerations

Radiation therapy should be delivered only after evaluation of the mammography findings, the pathology findings, and the surgical procedures performed on the patient. The optimal combination of surgery and irradiation to achieve the dual objectives of local tumor control and preservation of cosmetic appearance varies from patient to patient. The optimal combination is determined by the extent, nature, and location of the tumor; the patient's breast size; and the patient's relative concerns about local recurrence and preservation of cosmetic appearance. Details about radiation therapy techniques are given in the original guideline document.

Follow-up Care Recommendations

Follow-up assessment of the results of breast conservation treatment should be provided by surgeons and oncologists experienced in that treatment as outlined in this standard, and it should also evaluate the cosmetic outcome as well as the functional consequences. The goals of a regular follow-up examination include the following:

1. Early detection of recurrent or new cancer, allowing timely intervention.
2. Identification of any treatment sequelae and appropriate interventions where indicated.
3. Provision of the individual practice with the database necessary to optimize treatment and compare outcomes against national standards.

Regular history and physical examination in conjunction with breast imaging are the cornerstones of effective follow-up care. Unfortunately, many patients perceive history and physical examination to be less important as reliable follow-up measures than sophisticated medical testing. Routine tests such as bone scan, chest x-ray, computed tomography (CT) scan, and liver function tests are not indicated for asymptomatic patients treated for DCIS. A public education effort is needed to address this problem.

The following evaluations should be performed by the physician at the cited intervals following the completion of treatment.

Examinations and Mammography

History and physical examination

Examination frequency, is directed toward the identification of local recurrence and new second primary tumors.

1. Every 6 months, years 1 to 5. (Some oncologists prefer every 6 months until after year 8, when the risk of local recurrence with breast conservation treatment begins to approach the risk of contralateral breast cancer.)
2. Annually thereafter.

Mammography

A goal of follow-up imaging of the treated breast is the early recognition of tumor recurrence. To prevent unnecessary biopsy, it is important to know that postoperative and irradiation changes overlap with signs of malignancy on a mammogram. The changes include masses (postoperative fluid collections and scarring), edema, skin thickening, and calcifications.

Postsurgical and radiation edema, skin thickening, and postoperative fluid collections will be most marked in the first 6 months. For most patients, radiographic changes will slowly resolve after the first 6 to 12 months and will demonstrate stability within 2 years.

In order to interpret the mammograms accurately and assess the direction of change, the current mammogram must be compared in sequence with the preceding studies. The diagnostic radiologist should carefully tailor mammographic studies of the treated breast to the surgical site by using special mammographic views in addition to routine mediolateral oblique and craniocaudal views. Magnification and spot compression can be used with any view to increase detailed visualization of the site of tumor excision and other areas. Magnification radiography is useful for classifying calcifications morphologically and quantitating them. Other special views may be useful in the assessment of the breast after conservation.

As postoperative masses resolve and scars form, a spiculated mass that mimics tumor may be seen on the mammogram. Additional radiographic projections of the site of tumor removal facilitate more confident radiographic interpretations.

Schedule of Imaging of the Treated Breast

1. A postoperative mammogram is essential to ensure that microcalcifications have been removed in patients having breast conservation treatment with or without irradiation. The site of the excision may be optimally evaluated with magnification radiography for residual microcalcifications if none are seen on routine views.
2. A baseline mammogram during the first 6 to 12 months following breast conservation treatment.
3. A mammogram at least annually thereafter, or at more frequent intervals as warranted by clinical or radiographic findings.

Schedule of Imaging of the Contralateral Breast

A mammogram should be performed annually, according to the guidelines endorsed by both the American College of Radiology and the American Cancer Society. More frequent intervals may be warranted by clinical or radiographic findings. (The risk of cancer is approximately the same for both the treated and the untreated breast.)

Evaluation of Sequelae

At the time of the first follow-up examination and serially thereafter, the physician should evaluate the patient for any treatment-related toxicities. This evaluation should include:

1. Assessment of the overall cosmetic result. A four-point scoring system is recommended for assessing the cosmetic result:

   Excellent: Treated breast is almost identical to untreated breast.

   Good: Minimal difference between the treated and untreated breasts.

   Fair: Obvious difference between the treated and untreated breasts.

   Poor: Major functional and esthetic sequelae in the treated breast.

2. Patient evaluation of results. The patient's evaluation of treatment outcomes in terms of psychological, functional, and cosmetic consequences should be taken into account in the follow-up process.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations were based primarily on a comprehensive review of published reports. In cases where the data did not appear conclusive, recommendations were based on the consensus opinion of the group.

Evidence base for treatment interventions:

Mastectomy: No prospective randomized trials have compared the treatment of ductal carcinoma in situ (DCIS) by mastectomy with treatment by breast conservation. Supporting literature includes studies from single institutions.

Breast-Conserving Surgery and Radiation Therapy compared to Breast Conserving Surgery Alone: Data from two prospective

randomized trials are currently available (the National Surgical Adjuvant Breast and Bowel Project (NSABP), protocol B-17, and the European Organization for Research and Treatment of Cancer (EORTC). Retrospective case series are also considered.

Breast-Conserving Surgery Alone: A number of studies have examined the outcome of treatment of DCIS by excision alone. Retrospective analyses were reported for a number of other studies.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General

- Effective multidisciplinary diagnosis and management of ductal carcinoma in situ (DCIS) of the breast
- Appropriate selection of patients for breast conservative surgery

Benefits of specific treatment options

- Mastectomy: Relapse rates, either regionally or systemically, of 1-2% have been reported for patients with both clinically evident and mammographically detected DCIS. Although mastectomy results in cure rates approaching 100%, it may be overtreatment for many patients with DCIS, particularly those with small, mammographically detected lesions.
- Breast-conserving surgery and radiation therapy: In 1997, updated results from the National Surgical Adjuvant Breast Project (NASBP) protocol B-17 were published. In this prospective randomized study, the rate of ipsilateral breast tumor recurrences was markedly reduced by breast irradiation among patients with a mean time in study of 90 months (range: 67-130 months). The incidence of invasive recurrence was 3.9% in the radiated group compared to 13.4% in the nonirradiated group (p=.000005). The incidence of recurrent DCIS was also significantly reduced, from 13.4% in the group with no radiation to 8.2% in the radiated group (p=.007). The overall survival did not differ between groups: 94% for patients treated by lumpectomy alone, 95% for lumpectomy and radiation therapy. In another prospective randomized trial initiated by the European Organization for Research and Treatment of Cancer (EORTC), the 4-year local relapse-free rate was 84% in the group treated with surgery only compared with 91% in women treated by postoperative radiotherapy (log rank p=0.005; hazard ratio 0.62). The crude incidence of breast tumor recurrence reported in retrospective series ranges from 4% to 18%. Deaths caused by breast cancer have been reported in up to 4% of patients treated in studies with a median follow-up of 10 years or fewer.
- Breast-conserving surgery alone: In a prospective randomized study the breast cancer recurrence rate at eight years was 26.8%, significantly higher than the rate observed for breast-conserving surgery with radiation therapy.

POTENTIAL HARMS

Risks associated with exposure to radiation

Subgroups Most Likely to be Harmed:

Patients with exposure to radiation

- Women with a history of collagen vascular disease, especially scleroderma and lupus erythematosus
- Women with previous therapeutic radiation to the breast or chest
- Pregnant women

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The standards of the American College of Radiology (ACR) are not rules but are guidelines that attempt to define principles of practice that should generally produce high-quality radiological care. The physician and medical physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to American College of Radiology standards will not ensure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of the other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.
- The significance of young age (less than 40 years) in breast tumor recurrence is controversial. Three studies have observed an increased risk of breast recurrence (approximately 25%) in young women with DCIS treated with conservative surgery and radiation when compared with older women (approximately 10%). However, three additional studies have found no correlation with young age and breast recurrence rates. The effect of age on local failure was analyzed in the National Surgical Adjuvant Breast and Bowel Project (NSABP) B24 trial. All patients received radiotherapy and were randomized to tamoxifen 20 mg daily for 5 years or placebo. The rate of ipsilateral breast recurrence in women age 49 or less in the placebo arm was 33.3 per 1,000 per year, compared to 13.03 per 1,000 per year for those age 50 and older. For those taking tamoxifen, recurrence rates were 20.77 per 1,000 per year for those age 49 and under, and 10.19 per 1,000 per year for those in the older age group. This randomized trial provides convincing evidence that young age is associated with a higher rate of breast recurrence.
- A similar controversy exists regarding a positive family history of breast cancer, and breast tumor recurrence rate. The impact of a positive family history of breast cancer on treatment options in women with ductal carcinoma in situ (DCIS) requires further evaluation.
- The contribution of various pathologic factors (histologic subtype, nuclear grade, necrosis) to the risk of breast recurrence in patients treated with conservative surgery and radiation is controversial.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Standards that are approved at each ACR Annual Meeting are distributed to the membership by a separate mailing for implementation in their practices. All American College of Radiology (ACR) Standards are also available to members and the general public on the College's Web site: www.acr.org.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Standards for the management of ductal carcinoma in situ of the breast (DCIS). CA Cancer J Clin 2002 Sep-Oct;52(5):256-76. [104 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2001)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

American College of Radiology; American College of Surgeons; College of American Pathologists; Society of Surgical Oncology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

American College of Radiology Members: Eric A. Strom, MD (Co-Chair); Lawrence W. Bassett, MD; D. David Dershaw, MD; Barbara L. Fowble, MD; Jay R. Harris, MD

American College of Surgeons Members: Monica Morrow, MD (Co-Chair, Senior Editor); S. Eva Singletary, MD; David P. Winchester, MD

College of American Pathologists Members: Frances O´Malley, MD; Stuart J. Schnitt, MD

American College of Radiology Staff: John Curry; Marie Zinninger; Sandra Smith Bjork

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American College of Surgeons - Medical Specialty Society
College of American Pathologists - Medical Specialty Society
Society of Surgical Oncology - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously released version (CA Cancer J Clin 1998 Mar/Apr;48[2]:108-28).

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 25, 1999. The information was verified by the guideline developer as of May 12, 2000. This summary was updated by ECRI on September 17, 2002. The updated information was verified by the guideline developer on September 30, 2002.

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